

March 17, 1999

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To: Dockets Management Branch, HFA-305

From: Vivian Gilliam, HFS-215

The information enclosed should be placed in the Docket No. 96F-0176, FAP 6B4505.

Any additional information needed may be addressed to Vivian Gilliam at (202) 418-3167.

Sincerely,

Vivian Gilliam
Direct Additives Branch, HFS-215
Division of Petition Control
Center for Food Safety
and Applied Nutrition

Attn: Jennie Butler

96F-0176

EAL

Appendix IX

ENVIRONMENTAL ASSESSMENT

1. Date: March 1, 1999
2. Name of Petitioner: Toray Industries (America), Inc.
3. Address: All communications on this matter are to be sent in care of Counsel for Petitioner, Jerome H. Heckman, Keller and Heckman, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4110.
4. Description of the Proposed Action:

The action requested in this Petition is the amendment of the Food Additive Regulations, at 21 C.F.R. §§ 177.1390 and 177.1500, to permit the safe use of Nylon 6/12 manufactured by copolymerization of a ratio of at least 85 weight-percent of epsilon-caprolactam and not more than 15 weight-percent of omega-lauro lactam in non-food-contact layers of multilaminate films intended for use in contact with food and in non-food-

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contact layers of rigid multilaminate constructions where the outer layers are made of polypropylene intended for use in contact with food of all types under Conditions of Use A, B, C, D, E, F, G, and H as defined under 21 C.F.R. § 176.170(c), Table 2. Nylon 6/12 resins complying with Section 177.1500(a)(13)(ii) are currently cleared as non-food-contact layers at temperatures not to exceed 212°F. If the requested action is taken, an improved product will be available for use in food packaging applications to compete with, and replace, existing products.

Nylon 6/12 for use as non-food-contact layers at temperatures not to exceed 212°F, as currently permitted, is produced by Toray Industries at its production facilities in Nagoya, Japan. The resin that is the subject of this Petition is the identical material produced at the same plant. Nylon 6/12 will be used as a non-food-contact layer of multilaminate films and of multilaminate polypropylene rigid containers. The laminates are converted to bags and/or other packaging materials at Toray Industries' customers' facilities. Foods are placed in the pouches by food processors, and the final products are distributed throughout the United States.

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The food packaging material that is the subject of this Petition will be used in patterns corresponding to national population density, and will be widely distributed across the country. Consequently, it is expected that disposal will occur nationwide, with about 80% of the materials ultimately being deposited in land disposal sites, and with about 20% being incinerated.

The types of environments present at and adjacent to these disposal locations are the same for the disposal of other retail food packaging material in current use. Therefore, there are no special considerations concerning the environment surrounding the disposal of Nylon 6/12 when used as proposed by this Petition.

5. Identification of Chemical Substance That Is the Subject of the Proposed Action

The identification of the resin that is the subject of this Petition, and the raw materials used to prepare the resin, are provided in the following table:

TABLE I

CHEMICAL NAME	CAS NO.	MOLECULAR WEIGHT	EMPIRICAL FORMULA	PHYSICAL DESCRIP.
Nylon 6/12	25191-04-2	47200 (M_w)	$(C_{12}H_{23}NO \cdot C_6H_{11}NO)_x$	solid
CAPROLACTAM	105-60-2	113	$C_6H_{11}NO$	White powder
LAUROLACTAM	947-04-6	197	$HN-(CH_2)_{11}-CO$	White solid

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6. Introduction of Substances into the Environment

The action requested by this Petition is to expand the cleared conditions of use under which Nylon 6/12 resin may be used as a non-food-contact layer in laminate structures. No extraordinary circumstances exist at the manufacturing facility or are reasonably expected to occur in Nylon 6/12 production that would result in emissions significantly affecting the quality of the environment.

Data on the quantity of Nylon 6/12 produced for current applications, including both food-contact and non-food-contact applications, and the quantity of Nylon 6/12 expected to be used in new applications resulting from promulgation of the proposed regulation are presented in Appendix X, Confidential Environmental Information.

Disposal by the ultimate consumer of food packaging materials containing Nylon 6/12 copolymers will be by conventional garbage disposal methods, resulting in delivery of the waste to sanitary landfills and incinerators. Since Nylon 6/12 resin is prepared from only carbon-, oxygen-, hydrogen- and nitrogen-containing materials, the combustion products expected as a result of the incineration of this resin do not pose any toxicity concerns. Specifically, the quantity

of nitrogen oxides that may be released as a result of the incineration of Nylon 6/12 resins produced as a result of the requested action will not exceed 0.00011% of the total nitrogen oxides emitted in 1985.^{1/} When laminates containing Nylon 6/12 copolymers are added to sanitary landfills, no significant quantity of leachate is expected to enter the environment. This conclusion is based on the extremely low levels of migration of extractable components from the nylon copolymers under highly exaggerated (from an environmental standpoint) exposure conditions (250°F for 2 hours, followed by long-term storage at 120°F) as shown in Section B of this Petition. Under the more moderate conditions anticipated in landfills, no significant quantities of Nylon 6/12 components are expected to migrate into landfill leachate. Moreover, even if very small amounts of substances migrate from the food packaging into landfill leachate, we expect extremely low quantities to actually enter the environment; this finding is based on the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills.^{2/}

^{1/} See Confidential Environmental Information, Appendix X.

^{2/} See 40 C.F.R. Part 258. EPA's regulations require new municipal solid waste landfills and lateral expansions of existing landfills to have ground water monitoring systems as well as composite liners and leachate collection systems to prevent leachate from entering ground and surface water.

(continued...)

To summarize the pertinent data, an average of .042 milligrams (mg) caprolactam/in² (24 ppm) and 0.0017 mg/in² lauro lactam were found in distilled water after extraction for 2 hours at 250°F followed by exposure at 120°F for 240 hours. Nylon 6/12 oligomers were found in extracts at an average concentration of 0.0025 mg/in².

It is also clear that there will be no new or additional substances entering the environment as a result of the use of the additive which is the subject of this Petition. Nylon 6/12 is intended to replace other materials currently used as the non-food-contact layer in food-contact structures. Since the subject additive is intended to be used and disposed of in a manner identical to the products which it will replace and since Nylon 6/12 is currently used in food packaging applications, no new or additional substances will enter the environment at the site of production or disposal as a result of the proposed action. Therefore, there will be no increase in pollution (air, water, or soil) if the proposed action to

^{2/}(...continued)

Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993, are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

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amend the conditions of use of the product as a non-food-
contact layer in laminated films.

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7. Fate of Emitted Substances in the Environment

The following physical/chemical data are useful for estimating the environmental concentration and mobility of Nylon 6/12 monomers and oligomers that may enter the environment as a result of disposal of the finished food-contact articles:

Table III

Physical/Chemical Properties of Nylon 6/12
and Component Monomers

Compound	Solubility	n-Octanol/ Water	Vapor
		Water Part.*/ (22°C)	Pressure (Pascal)
Caprolactam	Soluble	0.93	28.8 at 69°C
Lauro lactam	.0025% @ 25° C.	N/A	1 hPa at 155° C.
Nylon 6/12	Insoluble	N/A	N/A

* Partition Coefficient
N/A = not available

As shown in Section 2 of the Petition, there is no detectable migration of Nylon 6/12 oligomers (except for Nylon 6/12 dimer) from multilayer laminate films even under extreme temperatures of use (250°F for 2 hours followed by 120°F for 240 hours). Under the less severe temperatures expected in landfills and other disposal operations, there is no reasonable expectation that Nylon 6/12 oligomers will migrate from the packaging materials into the environment.

Similarly, while residual caprolactam, laurolactam and Nylon 6/12 dimer did migrate under the high temperature exposure conditions discussed in the extraction studies, the studies also showed that no additional material migrated under room temperature conditions following extended storage. In addition, the n-octanol/water partition coefficient for caprolactam at 22°C shows that little, if any, caprolactam is expected to partition from laminated articles into groundwater that contacts these food packaging articles in landfill disposal. Similarly, the higher molecular weight of the dimer and lower rate of migration under high temperatures makes it unlikely that any dimer will partition from the laminated packaging materials. Thus, no significant leaching of caprolactam, laurolactam or Nylon 6/12 dimer is anticipated

under normal landfill conditions.

On the basis of the data, it is apparent that there will be no significant adverse environmental effects from the disposal of Nylon 6/12.

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8. Environmental Effects of Released Substances

Toxicological studies on caprolactam that have been reviewed by FDA include acute toxicity studies, subchronic studies in rats and dogs, teratology studies in rats and rabbits, three-generation reproductive toxicity studies in rats, and carcinogenicity studies in rats and mice. Data regarding the toxic effects of laurolactam include acute toxicity studies and subchronic studies in dogs and rats. Subchronic feeding studies on oligomers of Nylon 6 in rats and subacute studies on Nylon 12 oligomers also have been evaluated. The relevant toxicological data, all available in the Agency's files, are incorporated herein by reference.

FDA's most recent evaluation of the toxicological data with regard to Nylon 6/12 extractables was conducted in its review of FAP No. 3B3743, which dealt with Nylon 6/12 prepared by reacting a minimum of 80 weight-percent of epsilon-caprolactam with no more than 20 weight-percent of omega-laurolactam. (58 Fed. Reg. 32,609 (June 11, 1993)).

Based on these data, it is clear that any minute levels of caprolactam, laurolactam or Nylon 6/12 oligomers that may

enter the environment. The use of Nylon 6/12 will
not have any adverse effect on the environment.

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9. Use of Resources and Energy

Since other chemically similar products currently available are being used in similar applications, approval of the expanded use of the additive will not cause any overall increase in petroleum usage or any other environmental effects. Indeed, the Nylon 6/12 copolymer is made using the same equipment currently used to produce Toray Industries current Nylon 6/12 polymers. Since the nylon copolymer will be used in place of other polymeric materials, e.g., nylon 6 and ethylene-vinyl acetate copolymers, there will not be a significant increase in the consumption of natural resources. The proposed action will not have an impact on established plastics recycling programs because multilaminate films containing Nylon 6/12 are not expected to enter the recycling stream.^{3/} Multilaminate films are not recycled because they are made from many different resins that are not specifically identified on

^{3/} Characterization of Municipal Solid Waste in the United States: 1996 Update. Report No. EPA 530-R-97-015, May 1997, Washington D.C. (Table 7).

the finished packaging material^{4/} and because they may be contaminated with food residues.

We do not expect that the use of Nylon 6/12 with polypropylene rigid constructions will adversely affect polypropylene recycling. We anticipate that only a very small fraction of food-packaging material using the Nylon 6/12 will be recycled after use by consumers.^{5/} The recycled end products would be non-food-contact items such as furniture, pallets, bird feeders, and carpets.^{6/}

^{4/} Under the resin identification code (RIC) parameters developed by The Society of the Plastics Industry, Inc., and incorporated into the RIC statutes of 39 states, rigid plastic containers employing Nylon 6/12 as a non-food layer would be labeled as "7-Other." Therefore, containers produced in accordance with the proposed regulation would be separated from non-laminate containers which are labeled with the appropriate code for the resin used to produce the container, e.g., "1-PETE" or "2-HDPE".

^{5/} See Characterization of Municipal Solid Waste in the United States: 1996 Update. Report No. EPA 530-R-97-015, May 1997, Washington D.C. (Table 7); see also note 4, above.

^{6/} Robert A Bennett, "Recycled Plastics, Product Applications and Potential," Page 35 in *Emerging Technologies in Plastics Recycling*, Gerald D. Andrews and Pallatheri M. Subramanian, Eds., ACS Symposium Series 513, American Chemical Society, Washington, D.C., 1992.

10. Mitigation Measures

There are no adverse environmental effects to be anticipated if the requested action is taken. Thus, no measures are required to avoid or mitigate potential adverse environmental impacts associated with the proposed action.

11. Alternatives to the Proposed Action

The alternative to "approving" the Nylon 6/12 additive which is the subject of this petition for use at temperatures slightly higher than those presently permitted for use as a non-food-contact component is to "not approve" the use of the additive for such purposes.

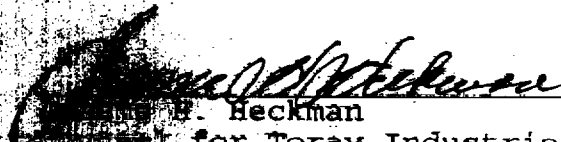
12. List of Preparers

- a. Holly H. Foley, B.S., Staff Scientist,
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Suite 500 West, Washington, D.C. 20001.
- b. Jerome H. Heckman, J.D., Attorney, Keller and
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13. Certification

The undersigned certifies that the information presented is true, accurate, and complete to the best of his or her knowledge.

Date: March 1, 1999


Charles B. Heckman
Attorney for Toray Industries
(America), Inc.

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14. References

All data referred to in the Environmental Assessment
are contained elsewhere.

15. Appendices

Attached with the original submission of this environmental assessment is a letter of the Plant Manager of the Nagoya Plant, Toray Industries, to the City of Nagoya, demonstrating compliance with applicable emission limits. An english translation of the letter is also attached.

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FROM KELLER AND HECKMAN